

**K180430 Digistat Smart Central**Nov 23, 2018  
280 days to decisionK180430 · Product code: **MSX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180430/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Feb 16, 2018
Decision date	Nov 23, 2018
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ascom Ums Srl Unipersonale</b>
Location	Scandicci (Fi), IT
Contact	Paolo Burchietti
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Speed TO Market, Inc.</b>
Contact	Thomas Kroenke

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180430/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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